NO. 91-1064

IN THE

Supreme Court of The United States

OCTOBER TERM, 1991

NICK & BARBARA LOZIER,

Petitioners

v.

F. BRANTLEY SCOTT, JR., M.D.,

Respondent

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR RESPONDENT IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED FOR REVIEW

1. Whether the petitioners waived assertion of their informed consent claim, including federal regulations regarding informed consent, by voluntarily withdrawing their informed consent claim at trial and by failing to request jury submissions regarding informed consent.

2. Whether the petitioners waived any complaint regarding jury instructions by their failure to object at trial.

3. Whether, under Texas tort law, consent to the intentional tort of battery must be in writing.

4. In the alternative, assuming that the petitioners did not waive their informed consent claim, whether the State of Texas voluntarily incorporated 21 C.F.R. § 50.27 as the standard for documenting informed consent in medical liability cases.

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STATEMENT OF THE CASE

At the age of seventeen, Nick Lozier (plaintiff at trial, petitioner here) was involved in a serious automobile accident that crushed his pelvis and severed his urethra, resulting in urinary retention and diminished sexual function. Tr. vol. 16, p. 16-18, 93-94; vol. 19, p. 16. Periodic medical treatment was required after the accident to alleviate the effect of scar tissue blocking Mr. Lozier's urethra, which would leave him temporarily incontinent. Tr. vol. 16, p. 94. Eventually, a procedure performed by Dr. Ralph Hopkins in Wyoming rendered Mr. Lozier both incontinent and unable to obtain an erection. Tr. vol. 12, p. 403; vol. 17, p. 105; vol. 19, p. 19-25. Mr. Lozier conceded at trial that he was unable to obtain an erection following the procedure by Dr. Hopkins. Tr. vol. 17, p. 103-105.

Mr. Lozier was referred by Dr. Hopkins to Dr. F. Brantley Scott, Jr. (defendant at trial, respondent here), now deceased, in Houston, Texas for treatment of both urinary incontinence and impotence. Tr. vol. 11, p. 282; vol. 17, p. 123; vol. 19, p. 45. Dr. Scott was to implant an artificial urinary sphincter to give Mr. Lozier control of his urine and also agreed to evaluate Mr. Lozier for implantation of an inflatable penile prosthesis (the Hydroflex) to enable Mr. Lozier to obtain an erection. Tr. vol. 10, p. 92.

Dr. Scott obtained Mr. Lozier's consent for implantation of the Hydroflex penile prosthesis after discussing the procedure with him in detail on several occasions. Tr. vol. 10, p. 92; vol. 12, p. 324-330; vol. 17, p. 193-197. On January 24, 1984, after Mr. Lozier had been pre-medicated for surgery, the charge nurse informed Dr. Scott that a consent form for the Hydroflex procedure had not been signed. Tr. vol. 12, p. 330-331. To avoid the risks inherent in a second surgery, and because Mr. Lozier had stated his consent for the penile prosthesis, Dr. Scott notated in the medical chart acknowledgment that informed consent had been obtained and proceeded with the surgery. Tr. vol. 12, p. 332.

Nick and Barbara Lozier (Nick's wife) brought this action against Dr. Scott pursuant to Texas law alleging battery, lack of informed consent and negligent pre-surgical work-up. Joint Pre-trial Order, Tr. vol. 3, tab 21. The federal district court obtained jurisdiction to preside over the case because the parties were in complete diversity. 28 U.S.C. § 1332. *See,* Tr. vol. 3, tab 21, p. 373. The Loziers also brought suit against Dr. Ralph Hopkins in Wyoming state court. The Loziers claimed, in the alternative, that Dr. Hopkins and Dr. Scott each caused Mr. Lozier's impotence. Tr. vol. 17, p. 105, 111.

The Loziers' claim against Dr. Hopkins was dropped because limitations barred recovery against him and the

Loziers proceeded only against Dr. Scott. Tr. vol. 18, p. 260. However, before dismissing his claim against Dr. Hopkins, Mr. Lozier executed an affidavit that was filed in the Wyoming state court. In his sworn affidavit, Mr. Lozier claimed he was *rendered impotent by Dr. Hopkins' treatment* (which *preceded* treatment by Dr. Scott). Tr. vol. 17, p. 114, 214; vol. 18, p. 253. This admission by Mr. Lozier proved ruinous to his case against Dr. Scott. The very foundation of Mr. Lozier's claim was that he *was not impotent* prior to treatment by Dr. Scott and, therefore, would not have consented to implant of a penile prosthesis. *See e.g.,* Tr. vol. 17, p. 83-89.

As evidence was presented, it became apparent that this was not an informed consent case. Mr. Lozier's position was not that he would not have consented to implant of the penile prosthesis had he been apprised of some undisclosed risk (informed consent), but that he was not impotent and did not consent to the implant, which would constitute a battery under Texas law. Tr. vol. 16, p. 48-52.

After the close of the Loziers' case, Dr. Scott presented the court with a motion for directed verdict, arguing that the elements of an informed consent cause of action were not present. Tr. vol. 21, 2-3. In response, the Loziers voluntarily withdrew their informed consent claim and agreed to proceed with only battery and negligent presurgical work-up. Tr. vol. 21, p. 5. The Loziers did not request that questions to support recovery for lack of informed consent be submitted to the jury.

At the close of the evidence, the district court correctly instructed the jury that Texas civil battery law did not require that consent be in writing. After deliberation, the jury found that Mr. Lozier did consent to implantation of the Hydroflex prosthesis and that Dr. Scott was not negligent in his pre-surgical work-up. Tr. vol. 1, tab 81. All other jury

interrogatories were conditioned upon a finding of negligence or of no consent and were therefore not answered by the jury. The district court entered judgment for Dr. Scott based upon the jury verdict and the Loziers appealed to the United States Court of Appeals for the Fifth Circuit. The Fifth Circuit affirmed in an unpublished opinion. Petition for Writ of Certiorari, Appendix No. 1.

SUMMARY OF THE ARGUMENT

A petition for writ of certiorari is to be granted only if special and important reasons therefor exist. SUP. CT. R. 10.1. The petitioners assert that an important question of federal law exists pursuant to Rule 10.1(c), believing that the concept of federal preemption somehow imposes upon the states the duty to provide civil tort recovery for failure to comply with Federal Food and Drug Administration (FDA) regulations. Fortunately, however, the doctrine of federal preemption does not operate to so pervasively usurp the historic right of the states to govern civil tort recovery for claims brought under state law. Therefore, resolution of the relevant issues in this diversity case involves interpretation of a Texas statute, the Texas Medical Liability and Insurance Improvement Act, TEX. REV. CIV. STAT. art. 4590i. Because state law, and not federal law, controls in this case, there is no basis for review by this Court. SUP. CT. R. 10.1.

At trial, the Loziers voluntarily withdrew their informed consent claim and proceeded against Dr. Scott with only battery and negligent pre-surgical work-up claims. As a result, this was no longer an informed consent case and no informed consent provision, whether originating under federal or state law, remained applicable. In particular, whether a writing was required to document informed consent pursuant to federal regulation had no bearing on this case. The

only remaining issue was whether oral consent was a sufficient defense in Texas to the intentional tort of battery.

The Loziers brought this diversity action under Texas tort law. If the Loziers had not dropped their informed consent claim, the issue in this case would have been whether a plaintiff could recover *under Texas tort law* for the defendant's failure to comply with the writing requirement contained in 21 C.F.R. § 50.27. Stated more specifically, the question to be decided would have been whether Texas informed consent law voluntarily incorporated 21 C.F.R. § 50.27 as a basis for tort recovery. Because the Loziers did withdraw their informed consent claim, however, the issue at trial was whether Texas *battery* law required that consent be in writing to be effective.

The Loziers have mischaracterized Dr. Scott's position in this case as, "[T]he subject may give his informed consent orally" pursuant to FDA regulations, particularly 21 C.F.R. § 50.27. Petition, p. 17. On the contrary, there is no doubt that 21 C.F.R. § 50.27 requires that informed consent for implantation of investigational devices be documented in writing. However, this case was not an administrative proceeding to enforce compliance with FDA regulations. Therefore, Dr. Scott's failure to comply with 21 C.F.R. § 50.27 was not dispositive.

The Loziers still maintain that Dr. Scott's position that FDA regulations do not obligate the states to provide for tort recovery for violation of 21 C.F.R. § 50.27 "render[s] the express words of 21 U.S.C. § 360j(g) and 21 C.F.R. § 50.27(a) utterly meaningless." Petition, p. 29. However, the regulations neither create a federal cause of action, nor obligate the states to provide one. The goal for involvement in the investigational process is FDA approval of the particular device. Failure to comply with the FDA regulations, including 21 C.F.R. § 50.27, can result in withdrawal of the

investigational device exemption, an administrative remedy. 21 C.F.R. § 812.30(b)(4). Therefore, failure to document informed consent in writing could frustrate FDA approval of the device. The absence of a state tort remedy for failure to comply with these regulations does not hinder the FDA's ability to enforce compliance with its rules. Therefore, the doctrine of federal preemption simply does not apply and the requisites for review by this Court do not exist in this case.

ARGUMENT AND AUTHORITIES

I. FDA Regulations Governing Informed Consent For Investigational Devices Are Not Relevant To This Case Because The Petitioners Voluntarily Withdrew Their Informed Consent Claim At Trial.

There is a fundamental distinction between a cause of action for battery, which is an intentional tort, and a cause of action for lack of informed consent, which is founded in negligence. *See, Wilson v. Scott*, 412 S.W.2d 299, 302 (Tex. 1967). An informed consent claim is based upon failure to reasonably disclose the material risks of a procedure. *Jones v. Papp*, 782 S.W.2d 236, 241 (Tex. App. — Houston [14th Dist.] 1989, writ denied). The emphasis in informed consent cases is whether disclosure was adequate. *Karp v. Cooley*, 493 F.2d 408, 419-420 (5th Cir.), *cert. denied*, 419 U.S. 445 (1974). All actions for informed consent in Texas are governed by the Texas Medical Liability and Insurance Improvement Act, TEX. REV. CIV. STAT. art. 4590i (the "Texas Medical Liability Act"). The Medical Liability Act, in conjunction with the case law, establishes the elements which a plaintiff must prove to recover for lack of informed consent.

The elements of the intentional tort of battery, on the other hand, are established by the common law of Texas. For

there to be a battery, there must be an intentional act. RESTATEMENT (SECOND) OF TORTS § 13. There can be no battery if the actor was merely negligent. RESTATEMENT (SECOND) OF TORTS § 18(2). Under Texas law, consent is an absolute defense to the intentional tort of battery.[1] RESTATEMENT (SECOND) OF TORTS § 13, Comment B (1965); *Moss v. Rishworth*, 222 S.W. 225, 226 (Tex. Comm'n App. 1920, holding approved). There is no requirement that consent be in writing and oral consent to surgery is an effective defense against a claim of battery. *See, Gravis v. Physicians and Surgeons Hosp. of Alice*, 427 S.W.2d 310, 311 (Tex. 1968).

During trial, in response to a motion for directed verdict by Dr. Scott, the Loziers voluntarily withdrew their assertion of an informed consent cause of action and agreed to proceed with only their battery and negligent pre-surgical work-up claims. Tr. vol. 11, p. 235; vol. 21, p. 5. The Loziers withdrew informed consent because the facts did not support its submission to the jury. Even Mr. Lozier admitted to discussing the risks of the procedure with Dr. Scott in detail. Tr. vol. 17, p. 193-197. No testimony was presented that a material risk of the penile implant procedure was withheld from Mr. Lozier. Rather, Mr. Lozier claimed that he was not impotent and, therefore, did not consent to the procedure, which would constitute a battery under Texas law.

During final argument, the Loziers reaffirmed that withdrawal of their informed consent claim had been voluntary. Mr. Robert J. Swift (Dr. Scott's attorney) commented to the jury that the issue of informed consent had been resolved by

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[1] The Loziers' assertion that consent is an *affirmative* defense to battery, however, is not correct. *See* Petition, p. 28. Lack of consent is an element which the plaintiff must establish as part of his *prima facia* case. *Gravis v. Physicians and Surgeons Hosp. of Alice*, 427 S.W.2d 310, 311 (Tex. 1968).

the court. Mr. Arnold Vickery, an attorney for the Loziers, objected to Mr. Swift's characterization, stating that the informed consent issue "*was resolved by* ***us***." Tr. vol. 22, p. 2 (emphasis added). The court sustained Mr. Vickery's objection, explaining that the court "directed the verdict because [the Loziers] withdrew their claim." Tr. vol. 22, p. 2. Therefore, only battery and negligent pre-surgical work-up were submitted to the jury. The Loziers never requested that issues supporting recovery under an informed consent theory be submitted.[2]

Withdrawal of the Loziers' informed consent claim rendered both federal and state law regarding informed consent immaterial to this case and waived any error on appeal. FED. R. CIV. P. 61. The petitioners make a tortured attempt in their petition for writ of certiorari to tie a FDA regulation governing documentation of informed consent for implantation of investigational devices (21 C.F.R. § 50.27) to the elements of the intentional tort of *battery*. However, the Loziers waived any assertion of the FDA regulation that expressly governs documentation of *informed consent* by failing to preserve an informed consent claim at trial. Therefore, the only remaining issue at trial was whether oral consent was sufficient in Texas to avoid liability for a battery. Both the federal district court and the Fifth Circuit Court of Appeals held that oral consent to a battery was

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[2] The jury was asked, "Do you find by a preponderance of the evidence that Dr. F. Brantley Scott implanted a 'Hydroflex' penile prosthesis in Mr. Lozier without the consent of Mr. Lozier?" and "Do you find by a preponderance of the evidence that Dr. F. Brantley Scott was negligent in his preoperative work-up of Mr. Lozier?" Tr. vol. 1, tab 81. The jury answered "No" to both issues. The sufficiency of the evidence to support the jury's findings has not been challenged by the Loziers on appeal.

sufficient under Texas law. This leaves no "important question of federal law" to be decided by this Court. SUP. CT. R. 10.1(c).

II. The Petitioners Waived Any Claim Of Error Regarding Jury Instructions.

In one question presented for review, the Loziers assert that this Court should determine, "[W]hether the District Court erred in refusing to instruct the jury on the provisions of federal law . . .". Petition, p. ii. However, the record does not establish that the Loziers ever requested the district court to so instruct the jury.[3] Therefore, the Lozier's have waived any error regarding jury instructions on appeal.

The Loziers had the burden to provide the United States Court of Appeals for the Fifth Circuit with sufficient record to establish that error was committed and properly preserved at trial. FED. R. APP. P. 10(b)(1); *Smith v. United States*, 343 F.2d 539, 541 (5th Cir.), *cert. denied*, 382 U.S. 861 (1965). In the absence of sufficient transcript to affirmatively establish that error was committed and properly preserved, the Fifth Circuit had "no alternative but to affirm the decision of the district court." *McDonough Marine Serv., Inc. v. M/V Royal Street*, 608 F.2d 203, 204 (5th Cir. 1979).

In particular, to complain of error regarding jury instructions or interrogatories, the record on appeal must establish that the petitioners properly and timely objected to the jury charge at trial. FED. R. CIV. P. 51; *Farrar v. Cain*, 756 F.2d 1148, 1150 (5th Cir. 1985). Since the record in this case does not establish that the Loziers objected to the charge, the

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[3] The Loziers resisted providing even as much of the transcript as was available. It was upon motion by Dr. Scott, which the Loziers opposed, that any record other than limited excerpts of Dr. Scott's testimony were included. *See* Tr. vol. 1, tabs 104, 105, 107 and 109.

Fifth Circuit had to presume that no such objections were made. FED. R. CIV. P. 51. Therefore, even if writ of certiorari were granted, this Court could not consider whether the court's charge was appropriate. Because the Loziers failed to properly preserve error, the criteria for review by this Court have not been met. SUP. CT. R. 10.1.

III. The Doctrine Of Federal Preemption Is Not Applicable To This Case.

Because the Loziers did not plead a federal cause of action (Joint Pre-trial Order), Texas substantive law applies in this diversity case. *Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938). It is unusual that the Loziers, who were the plaintiffs at trial, would argue that a federal regulation preempted the state law under which they brought their claim. If, as the Loziers assert, federal regulations preempted Texas tort law, the state law under which the Loziers brought their claim would be nullified. *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 712-713 (1985). The result would be dismissal of their claim. *See, Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 244 (5th Cir. 1989).

As discussed *Infra* ¶ I, the Loziers voluntarily withdrew their informed consent claim at trial and made no request that interrogatories regarding informed consent be submitted to the jury. By withdrawing their informed consent claim, the Loziers waived assertion of any regulation regarding informed consent. However, the federal regulation which the Loziers now assert provides that a patient's informed consent for the implantation of an investigational device must be document in writing. Although withdrawal of their informed consent claim at trial defeats the Loziers' position on appeal, to fully brief all hypothetical issues, it will be presumed in this section that the Loziers did not waive their informed consent claim and that informed consent interrogatories were submitted for jury consideration.

Congress provided the preemption test for the regulation asserted by the Loziers (21 C.F.R. § 50.27) in 21 U.S.C. § 360k(a). *See, Smith v. Pingree*, 651 F.2d 1021, 1022-23 (5th Cir. 1981). Section 360k(a) is an express statement by Congress regarding the extent to which state law is preempted by the pertinent federal regulation. The courts look to other indicia of Congress' intent regarding preemption only in the absence of express language. *Hillsborough County*, 471 U.S. at 713.

Congress has provided that:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any *requirement* —
>
> (1) which is *different from, or in addition to*, any requirement applicable under this chapter to the device, *and*
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added). Therefore, Congress intended only to preempt "different" or "additional" "requirements" promulgated by the states. Section 360k(a) does not impose upon the states an obligation to provide for tort recovery for violations of federal regulations.

The Federal Food, Drug and Cosmetic Act (FDCA) was promulgated in part to establish guidelines for FDA investigation and approval of medical devices. 21 U.S.C. § 360j(g)(1). Regulations established pursuant to the FDCA detail the administrative procedure for the investigational process. One such regulation, 21 C.F.R. § 50.27, requires that informed consent for medical implant procedures be documented in writing. The Loziers sought to introduce a

copy of the 1989 version of 21 C.F.R. § 50.27 into evidence as PX63.[4] Tr. vol. 10, p. 110.

The goal for involvement in the investigatory process is ultimate FDA approval of the particular medical device. Failure to comply with the federal regulations, including 21 C.F.R. § 50.27, can result in withdrawal of the investigational device exemption, thereby defeating efforts to obtain FDA approval of the device. 21 U.S.C. § 360j(g)(5); 21 C.F.R. § 812.30(b)(4).[5] The absence of a tort remedy for failure to comply with the regulations does not impede the FDA's ability to enforce compliance with its rules. Therefore, although Texas could perhaps voluntarily incorporate FDA "standards" as a basis of tort recovery, its failure to do so does not create *requirements* that are *additional to* or *different from* those imposed by the FDA.

There is no conflict between 21 C.F.R. § 50.27 and Texas tort law and, therefore, the doctrine of federal preemption does not apply to this case. Compliance with the federal regulation was (and is) entirely consistent with Texas law. The federal regulation asserted by the Loziers, 21 C.F.R. § 50.27, required that informed consent for the implantation of investigational devices be documented in writing. Texas tort law neither required nor discouraged written documentation of informed consent. *See Infra* ¶ IV(B). Texas law simply did not provide for tort recovery for a physician's failure to comply with 21 C.F.R. § 50.27. Therefore, state

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[4] PX63 was not relevant becasue the event occurred in 1984, rather than 1989, and because the Loziers had withdrawn their informed consent claim. *Infra* ¶ I. The exhibit was offered for impeachment purposes only (Tr. Vol. 10, p. 128-129) and the attorney representing the Loziers was permitted to read the regulation to the jury. Tr. Vol. 10, p. 136-137.

[5] An investigational device exemption can be withdrawn or withheld if there is "reason to believe . . . informed consent is inadequate. . . ." 21 C.F.R. § 812.30(b)(4).

law did not create a requirement that was in addition to or different from the federal requirement regarding the documentation of informed consent and the doctrine of federal preemption did not apply.

Because the only relevant issue to be decided involved the interpretation of Texas law, the requirements of SUP. CT. R. 10.1, which provides the criteria for review on writ of certiorari, have not been met.

IV. The Pertinent Issue On Appeal Was Whether Texas Law Voluntarily Incorporated Federal Regulations As The Basis For Tort Recovery In Medical Liability Cases.

A. *Battery*

The Loziers assert that Dr. Scott should be liable under a theory of "battery *per se*" for failure to comply with an FDA regulation requiring that informed consent for investigational devices be documented in writing. Even though the jury found that Mr. Lozier consented to the procedure, the Loziers argue that Dr. Scott should be liable for battery as a matter of law for his failure to get a form signed documenting that consent.[6]

Under appropriate circumstances, the states may incorporate federal regulations as standards for tort recovery. As previously discussed *Infra,* ¶ III, however, the states are not compelled to do so. Therefore, the relevant issue on appeal was whether Texas law voluntarily incorporated the federal regulation asserted by the Loziers, 21 C.F.R. § 50.27, as the basis for tort recovery in medical malpractice actions. The federal district court's determination, which was entitled to

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[6] The sufficiency of the evidence to support the jury's finding that Mr. Lozier consented to the procedure has not been contested by the Loziers on appeal.

deference on appeal, was that Texas law did not. *See, Freeman v. Continental Gin Co.*, 381 F.2d 459, 466 (5th. Cir. 1967).

There has never been application in Texas of the negligence *per se* doctrine to an intentional tort.[7] The concept of negligence *per se* allows the courts to substitute a statutory "standard" for a jury determination of what the ordinarily prudent person would do under the circumstances. *Nixon v. Mr. Property Management Co., Inc.*, 690 S.W.2d 546, 549 (Tex. 1985). No "standard" of conduct is applicable, however, to an intentional tort such as battery. With an intentional tort, the actor's conduct is not compared against the "ordinarily prudent person". If the actor intended the offensive touching and the recipient did not consent, the actor is liable for battery regardless of what an "ordinarily prudent person" would have done. Therefore, application of the negligence *per se* doctrine to an intentional tort such as battery just simply does not fit.

B. *Informed Consent*

The Texas Medical Liability and Insurance Improvement Act created a Medical Disclosure Panel that has the duty to classify various surgical procedures into two categories: those requiring disclosure of risks (List A) and those requiring no disclosure (List B). TEX. REV. CIV. STAT. art. 4590i, § 6.04. If a procedure is classified under List A, the physician is required to disclose those risks the Panel determined to be material. TEX. REV. CIV. STAT. art. 4590i, § 6.05. If the specified disclosure is made in writing for List A procedures, a rebuttable presumption is created that disclosure was adequate. TEX. REV. CIV. STAT. art. 4590i, § 6.07(a).

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[7] In addition, no Texas case has ever applied the concept of negligence *per se* to an informed consent action.

In 1984, implantation of an inflatable penile prosthesis such as the Hydroflex device had not been classified by the Texas Medical Disclosure Panel and therefore was not contained on either List A or List B. Texas Medical Disclosure Panel, 7 Tex. Reg. 3473 (Sept. 24, 1982).[8] No presumption was created by written disclosure, or the lack thereof, if the procedure was one that has not yet been classified by the Panel. *Barclay v. Campbell,* 704 S.W.2d 8, 9 (Tex. 1986). Therefore, the provision cited as authority by the Loziers on page 23, footnote 4 of their petition to this Court is misleading. Section 6.06 of the Texas Medical Liability Act did not apply to this case because, in 1984, the procedure performed by Dr. Scott did not appear on the Panel's list requiring disclosure.[9]

The Medical Liability Act imposes the "duty otherwise imposed by law" upon physicians obtaining a patient's informed consent where the procedure has not yet been classified by the Medical Disclosure Panel. TEX. REV. CIV. STAT. art. 4590i, § 6.07(b). The Loziers argue that this language incorporates federal regulations as the criteria for documenting informed consent. However, the Texas Supreme Court has held that the phrase "duty otherwise imposed by law" in Section 6.07(b) simply refers to the duty imposed by Section 6.02 of the Medical Liability Act: "To disclose all risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent." *Peterson v. Shields,* 652 S.W.2d 929, 931 (Tex.

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[8] The list applicable to this case was effective beginning January 1, 1983. 7 Tex. Reg. 3453 (Sept. 24, 1982). The next revision to the list was not effective until January 1, 1985. 25 TEX. ADMIN. CODE § 601.1.

[9] In addition, documenting informed consent in writing only creates a rebuttable presumption that informed consent was obtained, even for those procedures on the Medical Disclosure Panel's list requiring disclosure. TEX. REV. CIV. STAT. art 4590i, § 6.07(a).

1983). Since the Texas Supreme Court is the highest authority regarding construction of Texas statutes *(Murdock v. City of Memphis,* 87 U.S. (20 Wall.) 590, 633 (1874)), this Court is not entitled to reinterpret Article 4590i. The considerations governing review on petition for writ of certiorari have not been met in this case because the relevant issue on appeal was interpretation of a Texas statute. SUP. CT. R. 10.1.

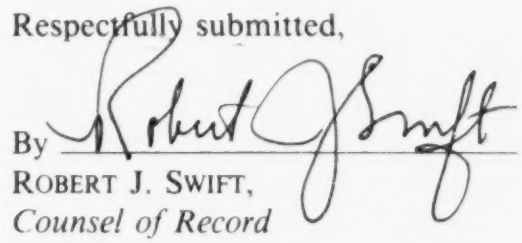
CONCLUSION

The concept of federal preemption is not relevant to this case. Texas law does not create a requirement that is different from or additional to FDA regulations simply because there is no recovery under Texas tort law for failure to comply with the federal regulation. *See,* 21 U.S.C. § 360k(a). In addition, the doctrine of federal preemption would operate to nullify the basis of the Loziers' claim, resulting in dismissal of their case against Dr. Scott, since their claim was brought pursuant to Texas tort law. Therefore, the relevant issue on appeal was whether Texas tort law voluntarily incorporated the relevant FDA regulations as the basis of tort recovery in medical malpractice cases. Resolution of that issue required interpretation of the Texas statute under which the Loziers brought their claim.

Both the Federal District Court for the Southern District of Texas and the Fifth Circuit Court of Appeals held that Texas law did not incorporate 21 C.F.R. § 50.27, the federal regulation asserted by the Loziers, as the basis for tort recovery in medical malpractice cases. The guidelines delineated in Rule 10.1 of the Rules of the Supreme Court for granting review on writ of certiorari have not been met. Because there is no important question of federal law for this Court to consider, Respondent F. Brantley Scott, Jr., M.D., deceased,

respectfully prays that this court deny the Lozier's Petition for Writ of Certiorari.

Respectfully submitted,

By 

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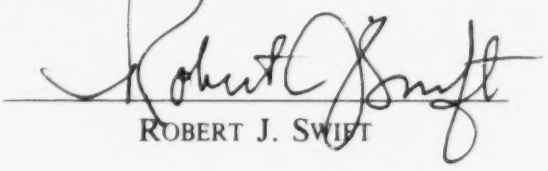
CERTIFICATE OF SERVICE

Pursuant to Rule 29 of the Rules of the Supreme Court of the United States, I certify that three copies of the Brief for Respondent have been served on Arnold Anderson Vickery, Vickery, Kilbride, Gilmore & Vickery, 2929 Allen Parkway, Suite 2770, Houston, TX 77019 via first-class postage prepaid, on this 21 day of January, 1992.



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